### **Electronic submissions**

### Improve efficiency

- Immediately usable
- Documents readily available
- Copy and paste
- Analysis ready
- Portable

#### **Current submissions**

- Learning curve
- Documents available incomplete, incompatible, complicated
- Copy and paste complicated
- Analysis limited
- Specialized hardware and software

#### **Future**

Long term fix

• Standardized tools and format

#### Short term fix

- Simple
- Sponsors use reviewer's tools
- Reviewers communicate needs in advance
- Balance needs with burden of sponsor

# Short term fix - example

## **Simple**

Collection of files

- Documents
- Data

#### **Documents** -reviewer's needs

- Complete
- Simple to use navigation tools
- Comprehensive, fast, search capabilities
- Ability to create hypertext linking
- Ability to write notes linked to pages
- Ability to copy images, text and tables
- Platform and word processor independent
- Easy to understand and use
- Use reviewer's tools

### Documents -Sponsor's burden

- Convert documents to pdf
- Linking

### **Linking - Reports**

#### **Minimal**

- Table of contents
- Listing of appendices
- Listing of tables

### **Optional**

- Internal linking
- External linking

### **Linking -CRF**

#### **Minimal**

- Individual file for each patient's CRF
- Listing of all CRFs by study and patient ID
- Bookmarks for each CRF domain by visit

### Data - reviewer's needs

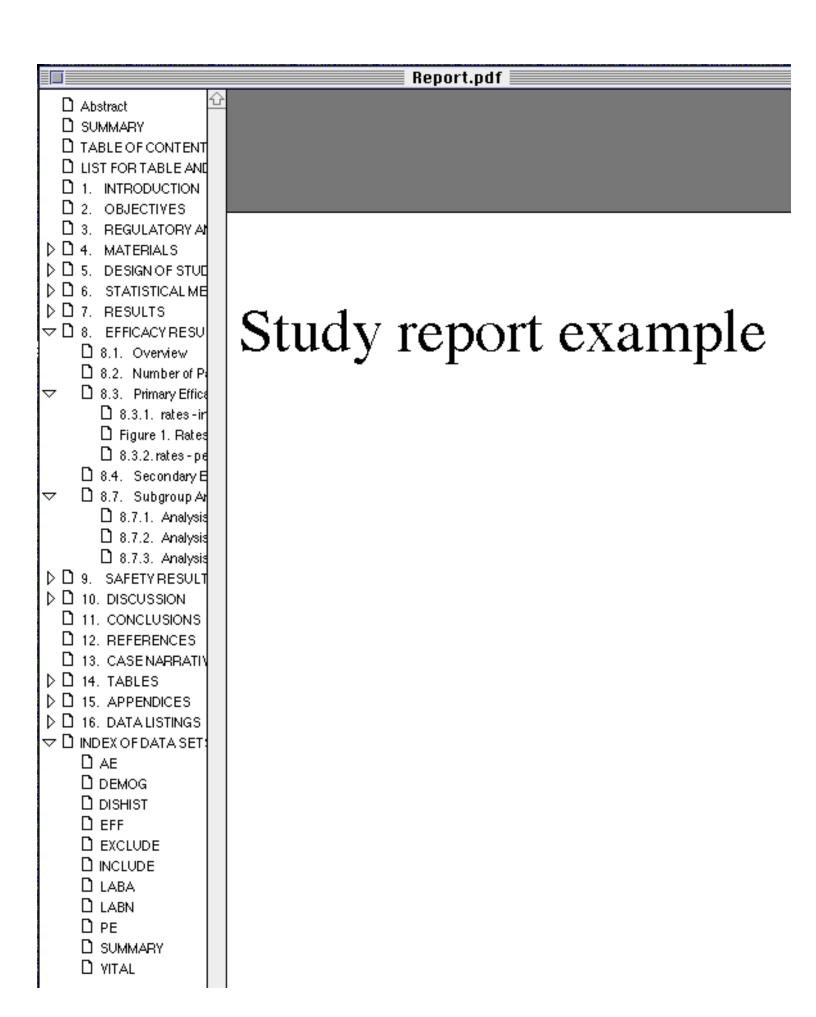
- Data sets in an analyzable formatData organized and easily found

#### Data - sponsor's burden

- Organize data by study and CRF domain
- Convert data into data set files
- Provide an index of all data sets in a pdf file
  - optional -Link the index to the data set file
- Provide a description of all variable (pdf file)

#### **Software and Hardware**

• Files on electronic media e.g. CD ROM, zip disk, Jaz disk



| CRF.pdf  |  |  |  |  |
|--|--|--|--|--|
| Adverse Events Background Informatio Chemistry Comments Other Medical Condition Drug Administration Drug Label Case Report Form Example Case Repor |  |  |  |  |

|                  | Electronic             | submission | <u> </u>          |
|------------------|------------------------|------------|-------------------|
|                  | <u>Name</u>            | Size       | Kind Lab          |
| ~                | CRFs                   | _          | folder 슙          |
| $\triangleright$ | Study 201 CRFs         | _          | folder            |
| $\triangleright$ | Study 202 CRFs         | _          | folder            |
| $\triangleright$ | Study 203 CRFs         | _          | folder            |
| $\overline{}$    | 🗀 Data sets            | _          | folder            |
|                  | 🗋 glossary.PDF         | 165K       | Acrobat™ Exchange |
| $\nabla$         | 🗀 Study 201 -data sets | -          | folder            |
|                  | ☐ AEs                  | 908K       | JMP document      |
|                  | Demographics           | 38K        | JMP document      |
|                  | ☐ Efficacy             | 21K        | JMP document      |
|                  | Efficacy data          | 78K        | JMP document      |
|                  | ☐ Labs                 | 293K       | JMP document      |
|                  | □ PROFILE              | 27K        | JMP document      |
|                  | ☐ Treatment            | 15K        | JMP document      |
|                  | Weekly efficacy        | 23K        | JMP document      |
|                  | Study 202 -data sets   | -          | folder            |
|                  | Study 302 data sets    | -          | folder            |
|                  | Summary data sets      | -          | folder            |
| $\nabla$         | ☐ Documents            | -          | folder            |
|                  | NDA index.pdf          | 2K         | Acrobat™ Exchange |
| $\nabla$         | ☐ Label                | -          | folder            |
|                  | ☐ Labe1.PDF            | 116K       | Acrobat™ Exchange |
| $\nabla$         | 🗀 Other                | -          | folder            |
|                  | 🗅 Other.pdf            | 3K         | Acrobat™ Exchange |
| $\nabla$         | Study reports          | -          | folder            |
|                  |                        | 1.1 MB     | Acrobat™ Exchange |
|                  | ☐ 3001.PDF             | 5.6 MB     | Acrobat™ Exchange |
|                  | 3003.PDF               | 10.5 MB    | Acrobat™ Exchange |
| $\nabla$         | Summaries              | -          | folder            |
|                  | ☐ ISE.pdf              | 2K         | Acrobat™ Exchange |
|                  | ☐ ISS.pdf              | 3K         | Acrobat™ Exchange |
|                  | NDA summary.pdf        | 3K         | Acrobat™ Exchange |
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